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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,568	10/10/2006	Nobuko Uchida	17810-519 NATL	4789

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EXAMINER	
SINGH, ANOOP KUMAR	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
09/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,568	UCHIDA ET AL.	
	Examiner	Art Unit	
	Anoop Singh	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-6, 7-8, 10-13, 14, 16-20, 28-30, 34-42, 46, 48, drawn to a method of producing a population enriched human pancreatic stem, method comprising contacting pancreatic tissue, pancreatic cells, pancreatic-derived cells, with a monoclonal antibody that binds CD133; and further comprising the steps of further enriching a population from pancreatic tissue for pancreatic stem cells antibody that binds CD34 or CD45.

Group II, claims 1-7, 9, 11-13, 15-19, 21, 28-29, 31-33, 35-42, 47, 48 drawn to a method of producing a population enriched for human pancreatic stem, method comprising contacting pancreatic tissue, method comprising contacting pancreatic tissue, pancreatic cells, pancreatic-derived cells, with a monoclonal antibody that binds CD49f+; and further comprising the steps of further enriching a population with a second monoclonal antibody that binds CD34 or CD45.

Group III, claims 7-13, 19, 28-29, 37-42, 47, 48 drawn to a method of producing a population of from pancreatic tissue enriched for human pancreatic stem cell, method comprising contacting pancreatic tissue, pancreatic cells, pancreatic-derived cells, with a monoclonal antibody that binds CD133+ CD49f+ and further selecting with CD34-, CD45- or CD34-CD45-.

Group IV, claims 22-24, drawn to an antibody that specifically binds to the CD49f antigen, wherein said CD49f antigen specifically binds to the monoclonal antibody GoH3 or to the monoclonal antibody 4F10.

Group V, claims 25-27, drawn to an antibody that specifically binds to the CD133 antigen, wherein said CD133 antigen specifically binds to the monoclonal antibody AC133.

Group VI, claims 43-46, drawn to a method for producing a population enriched for human pancreatic lineage committed progenitor cells, comprising selecting from a population of primary pancreas tissues, the method comprising selecting from a population of pancreatic tissue, for those cells that are CD49f++CD9+ .

Group VII, claims 43-46, drawn to a method for producing a population enriched for human pancreatic lineage committed progenitor cells, comprising selecting from a population of primary pancreas tissues, the method comprising selecting from a population of pancreatic tissue, for those cells that are CD133f+CD9+.

Group VIII, claims 49, drawn to a pancreatic stem cell, wherein the pancreatic stem cell is CD133+CD49f+.

Group IX, claims 50-51, drawn to a pancreatic progenitor cell committed to the endocrine beta-cell lineage, wherein the progenitor cell is CD49f+CD9+ and Cd15-.

Group X, claim 52, drawn to a pancreatic progenitor cell committed to the endocrine .beta-cell lineage, wherein the progenitor cell is CD49f.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking groups I-X is selecting pancreatic tissue, pancreatic cells, pancreatic-derived cells with a monoclonal antibody that binds CD133 or CD49f. Abraham et al (Diabetes, June 2003, Vol. 52 (1), A357, IDS) teach a method of contacting nestin positive islet derived progenitor cells with CD34, 45, AC133, CD or 49f, and selecting cells based on immunoreactivity of these markers meeting the limitation of claim 1 (abstract). Therefore, the instant technical feature does not contribute over prior art.

Each invention is directed to distinct goal, which comprises the use distinct set of positive or negative marker to enrich a population of cell in order to achieve

its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: pancreatic tissue, pancreatic cells, pancreatic-derived cells, or primary gastrointestinal tissue or gastrointestinal-derived cells.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 1, 7, 14, 15, 19, 20, 21, 28, 30, 31, 37, 38, 43, 46, 47, 48, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 1, 7, 14, 15, 19, 20, 21, 28, 30, 31, 37, 38, 43, 46, 47 and 48.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: The cell derived from each source of species will be structurally distinct and will not be coextensive in patent and non patent literature. In addition, these species are not obvious variants of each other based on the current record.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: anti-CD133 antibody selected from the group consisting of monoclonal antibody AC133 and monoclonal antibody SC111.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 7, 14, 19, 20, 25, 28, 30, 37, 38, 46-47, 49, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 7, 14, 19, 20, 25, 28, 30, 37, 38, 46-47, 49.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: claims to the

different species recite the mutually exclusive characteristics of such species and structurally distinct. In addition, these species are not obvious variants of each other based on the current record.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: anti-CD49f antibody selected from the group consisting of monoclonal antibody GoH3 and monoclonal antibody 4F10.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 7, 15, 19, 21, 22, 28, 31, 37, 38, 46-47, 50 and 52, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 7, 15, 19, 21, 22, 28, 31, 37, 38, 46-47, 50 and 52.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: different species recite the mutually exclusive characteristics of such species and structurally

distinct. In addition, these species are not obvious variants of each other based on the current record.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: population containing pancreatic tissue, pancreatic cells, pancreatic-derived cells, or primary gastrointestinal tissue or gastrointestinal-derived cells is obtained from a suspension culture, an adherent monolayer culture, a pancreatic explants, or a gastrointestinal explants.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 7, 15, 19, 21, 22, 28, 31, 37, 38, 46-47, 50 and 52, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 7, 15, 19, 21, 22, 28, 31, 37, 38, 46-47, 50 and 52.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: different species

recite the mutually exclusive characteristics of such species and structurally distinct. In addition, these species are not obvious variants of each other based on the current record.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to

the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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